## UNITED STATES DISTRICT COURT FOR THE DISTRICT OF RHODE ISLAND

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ALIFAX HOLDING SPA,

Plaintiff,

v.

ALCOR SCIENTIFIC INC.; and FRANCESCO A. FRAPPA,

Defendants.

C.A. No. 14-440 S

## MEMORANDUM AND ORDER

WILLIAM E. SMITH, Chief Judge.

Plaintiff Alifax filed this patent infringement action alleging, among other things, that Defendants Alcor and Frappa infringed two of Alifax's patents. One of the patents at issue in this case protects a diagnostic method for quickly measuring the erythrocyte sedimentation rate ("ESR") of a blood sample, as well as the sample's viscosity, elasticity, and density (the '679 Patent). The other patent at issue covers the apparatus designed to carry out the patented method (the '107 Patent). The ESR is a diagnostic test for general inflammation that helps diagnose infections and a variety of clinical conditions. Defendant Frappa allegedly had access to this intellectual property when he worked for Alifax, and allegedly shared it with Defendant Alcor when he began his employment there.

Defendants responded with three counterclaims, alleging that both of the patents at issue are invalid for failure to comply with 35 U.S.C. §§ 102, 103, and/or 112 and that Alifax intentionally interfered with Alcor's prospective contractual relations. The pretrial scheduling order provided for a claim construction phase within the discovery process. In Alifax's claim construction brief, it requests construction of one phrase that is used in two claims of the '679 Patent, and one phrase that is used in one claim of the '107 Patent. Defendants, in their claim construction brief, request construction of five terms or phrases that appear in the claims within one or both patents at issue.

The Court has thoroughly considered the parties' briefs and exhibits attached thereto as well as the technical tutorials and the arguments of counsel at the <a href="Markman">Markman</a> hearing. This Memorandum and Order provides the Court's construction of the seven claim terms and phrases raised and disputed by the parties.

# I. Claim Construction Principles

"[A] bedrock principle of patent law [is] that the claims of a patent define the invention to which the patentee is

<sup>&</sup>lt;sup>1</sup> <u>Markman v. Westview Instruments, Inc.</u>, 517 U.S. 370 (1996).

entitled the right to exclude."2 "The claim[s]... function[] to forbid not only exact copies of an invention, but products that go to 'the heart of an invention but avoid[] the literal language of the claim[s] by making a noncritical change[.]'"3 "Victory in an infringement suit requires a finding that the patent claim[s] 'cover[] the alleged infringer's product or process,' which in turn necessitates a determination of 'what the words in the claim[s] mean.'"4

"[T]he construction of a patent, including terms of art within its claim[s], is exclusively within the province of the court." The words of the claims are given their ordinary and customary meanings, unless a word or phrase is expressly defined in the patent to mean something else. "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art ["POSITA"] in question at the time of the invention, i.e., as of the

Innova/Pure Water, Inc. v. Safari Water Filtration Sys.,
Inc., 381 F.3d 1111, 1115 (Fed. Cir. 2004) (citation omitted).

<sup>&</sup>lt;sup>3</sup> <u>Markman</u>, 517 U.S. at 373-74 (quoting H. Schwartz, <u>Patent</u> <u>Law and Practice</u>, 82 (2d ed. 1995) (additional internal citation omitted)).

<sup>&</sup>lt;sup>4</sup> <u>Id.</u> at 374 (quoting Schwartz, <u>supra</u> n.3, at 80).

<sup>&</sup>lt;sup>5</sup> Id. at 372.

<sup>6</sup> Phillips v. AWH Corp., 415 F.3d 1303, 1312, 1316 (Fed. Cir. 2005).

effective filing date of the patent application." When the meaning of a claim term is apparent, then construing the terms "involves little more than the application of the widely accepted meaning of commonly understood words."

"Because the meaning of a claim term as understood by [a POSITA] is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks 'those sources available to the public that show what a [POSITA] would have understood [the] disputed claim language to mean."9 These sources include the intrinsic evidence of record: patent's specifications and claims as well as the patent's prosecution history. The Federal Circuit has acknowledged that "because prosecution history represents the an ongoing negotiation between the [Patent and Trademark Office] and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." 10 "Nonetheless, the prosecution history can often inform the meaning of the claim

<sup>&</sup>lt;sup>7</sup> <u>Id.</u> at 1313 (citing <u>Innova</u>, 381 F.3d at 1116).

 $<sup>^{8}</sup>$  <u>Id.</u> at 1314 (citing <u>Brown v. 3M</u>, 265 F.3d 1349, 1352 (Fed. Cir. 2001)).

<sup>&</sup>lt;sup>9</sup> Id. (quoting Innova, 381 F.3d at 1116).

 $<sup>^{10}</sup>$  <u>Id.</u> at 1317 (citing <u>Inverness Med. Switz. GmbH v. Warner</u> Lambert Co., 309 F.3d 1373, 1380-82 (Fed. Cir. 2002)).

language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." Statements in the prosecution history of a foreign patent, however, have been deemed irrelevant because they are made under different patentability requirements. 12

The context in which a term or phrase is used within these intrinsic sources "can be highly instructive." <sup>13</sup> To that end, the specification is considered "the single best guide to the meaning of a disputed term," and is usually dispositive of its meaning. <sup>14</sup> "In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In such circumstances, it is improper to rely on extrinsic evidence." <sup>15</sup> "The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct

<sup>11</sup> Id. (citing Vitronics Corp. v. Conceptronic, Inc., 90
F.3d 1576, 1582-83 (Fed. Cir. 1996)).

<sup>12</sup> Pfizer, Inc. v. Ranbaxy Labs. Ltd., 457 F.3d 1284, 1290
(Fed. Cir. 2006).

<sup>&</sup>lt;sup>13</sup> Phillips, 415 F.3d at 1314.

 $<sup>^{14}</sup>$  <u>Id.</u> at 1315 (quoting <u>Vitronics Corp.</u>, 90 F.3d at 1582).

<sup>15</sup> Vitronics Corp., 90 F.3d at 1583.

construction."<sup>16</sup> Extrinsic evidence such as dictionaries, treatises, expert opinions, or inventor testimony may be consulted and relied upon, but it is considered less reliable than the intrinsic patent record, and, as just stated, often not necessary.<sup>17</sup>

The established framework for claim construction includes two somewhat contrasting axioms: "a claim must be read in view of the specification and . . . a court may not read a limitation into a claim from the specification." The Federal Circuit has recognized that this seeming contradiction can be difficult to apply in practice, but encourages that "the line between construing terms and importing limitations can be discerned with reasonable certainty and predictability if the court's focus remains on understanding how a [POSITA] would understand the claim terms." 19

#### II. Indefiniteness

Defendants argue that three of the five terms it raises for construction are "indefinite" pursuant to 35 U.S.C. §  $112.^{20}$  The

<sup>16</sup> Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1249 (Fed. Cir. 1998).

<sup>&</sup>lt;sup>17</sup> Phillips, 415 F.3d at 1317-18.

<sup>18</sup> Innova, 381 F.3d at 1117 (citation omitted).

<sup>&</sup>lt;sup>19</sup> Phillips, 415 F.3d at 1323.

<sup>20 35</sup> U.S.C. § 112 states, in relevant part, that:

Supreme Court has held "that a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." [T]he definiteness requirement, so understood, mandates clarity, while recognizing that absolute precision is unattainable." Because indefiniteness can completely invalidate a claim or patent, several district courts have declined to address arguments on this point before the litigation reaches summary judgment proceedings, when the record is substantially developed. The Court will, however, address Defendants' arguments with respect

<sup>(</sup>a) In general.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

<sup>(</sup>b) Conclusion. -- The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

 $<sup>^{21}</sup>$  Nautilus, Inc. v. Biosig Instruments, Inc., 134 S. Ct. 2120, 2124 (2014).

<sup>&</sup>lt;sup>22</sup> Id. at 2129.

<sup>23</sup> See, e.g., Cipher Pharm. Inc. v. Actavis Labs. FL, Inc.,
99 F. Supp. 3d 508, 514 (D.N.J. 2015).

to indefiniteness in the discussion that follows.

## III. Disputed Claim Terms and Phrases

A. Alifax's Claim Phrase to Construe #1

Claim phrase	Alifax's proposed construction	Defendants' proposed construction	Court's construction
"the optical density or the absorbance acquired being processed to obtain said speed of sedimentation, viscosity, elasticity and density" ('679 Patent claims 1, 8, ECF No. 49-35.)	Using the acquired optical density or absorbance data to obtain correlated parameters including the speed of sedimentation, viscosity, elasticity and density	Plain and ordinary meaning	Processing the acquired optical density or absorbance data to obtain the speed of sedimentation, viscosity, elasticity and density

Alifax argues that the specification supports its proposed construction because a POSITA would understand both (1) that the four parameters measured by the patented method are mutually related; and (2) that the flow chart of the patented method provided in the '679 Patent indicates that the analysis and processing of the acquired data would occur immediately after the photometric data was acquired. Alifax also argues that simply applying the plain and ordinary meaning of the term would not resolve the parties' disagreement about the scope of the claim because "being processed to obtain" means "using the acquired" photometric data to obtain the four parameters listed, a meaning that a POSITA would understand.

According to Defendants, Alifax's proposed construction invites two errors. First, Defendants argue that, because Alifax included the precise four parameters measured by the method only after the Patent and Trademark Office initially rejected the patent application for indefiniteness, using the word "parameters" in the construction will create ambiguity and uncertainty where none currently exists. Second, the limitation "using" is a broad and unsupported synonym that is not in the claim language, so adding this limitation (or substituting it for "processing") does not have support from the specification. Defendants also argue that the proposed construction indicates that "correlated parameters" will be obtained, not that the patented parameters are limited to the speed of sedimentation, viscosity, elasticity, and density.

In response to Defendants' arguments, Alifax argues that Defendants are treating the four parameters measured oversimplistically because there is a relationship between the four parameters that is explained in the specification. The results from processing a sample include a single set of correlated results, not four independent parameters. Plaintiff also submits that it is not wedded to the word "using" and would be content with substituting "using" for "processing."

This phrase to construe appears in claims 1 and 8 of the '679 Patent. Claim 1 states, in relevant part, that:

A method to determine a speed of sedimentation, viscosity, elasticity and density of blood, said method being carried out by detecting a development over time of an optical density, or an absorbance, of a sample of blood, said sample being sent in the form of a flow inside a capillary container . . . , said detection being made in correspondence with any point along the length of said capillary container . . . and the optical density or the absorbance acquired being processed to obtain said speed of sedimentation, viscosity, elasticity and density wherein the method instantly interrupts the flow of the blood sample flowing inside said capillary container . . .

(Emphasis added on phrase to construe). For the purposes of construing the target phrase, claim 8 has the identical language.

The '679 Patent specification supports the "acquired optical density or absorbance data" part of Alifax's proposed construction because the description for the preferred embodiment for the patented method includes the following sentence: "At the same time as the pump . . . stops, the control and processing unit . . . commands the detector . . . to acquire the photometric data of optical density or absorbance." 24 Defendants do not dispute this portion of the proposed construction.

With respect to the use of the word "parameters" in the proposed construction, Defendants' argument that the term injects ambiguity and uncertainty into the claim has given the

<sup>&</sup>lt;sup>24</sup> '679 Patent col. 6, lines 10-12, ECF No. 49-35.

Court pause. A review of the entire patent reveals that the term "parameters" appears on its own throughout the specifications, as does "correlated parameters," as a form of short hand for the four measurements obtained by the patented method, i.e., the speed of sedimentation, density, viscosity, and elasticity. So the introduction of "correlated parameters" in Alifax's proposed construction does have support from the specifications.

The application for this patent, however, was initially rejected for indefiniteness based in part on the claim's use of the phrase "other parameters connected thereto": "Claims 1-9 are rendered indefinite because of the use of the language 'other parameters connected thereto.' It is unclear exactly what Applicant contemplates by this phraseology. Further clarification is required." Alifax responded with a revised application, replacing "other parameters connected thereto" with "viscosity, elasticity and density"; language which precisely identified the characteristics of the blood sample that would be measured in addition to the erythrocyte sedimentation rate. 27

<sup>25</sup> See e.g., '679 Patent col. 2, line 48; col. 3, line 12; col. 4, lines 11-12; col. 4, lines 45-46; col. 5, line 49; col. 6, lines 17-22.

<sup>&</sup>lt;sup>26</sup> PTO Office Action mailed April 5, 2002, ECF No. 48-14.

<sup>&</sup>lt;sup>27</sup> Applicant Resp. mailed July 5, 2002, ECF No. 48-4.

Thereafter, the patent examiner explicitly stated that the claims articulated in the patent application would be allowed because "the prior art does not teach or suggest a method to determine a speed of sedimentation, viscosity, elasticity, and density of blood . . . . "28

As the Federal Circuit has instructed, "the prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be."<sup>29</sup> Here, the patent applicant narrowed the scope of the claim to overcome the indefiniteness of "other parameters connected thereto" by articulating the precise characteristics the blood sample measured by the method. The Court understands that the specification informs that the viscosity, elasticity, and density of the blood sample are parameters that are considered correlated to the speed of sedimentation of the blood sample. Employing the term "correlated parameters" in the construction of the phrase at issue, however, could lead to the assumption later in this litigation that there are other characteristics of the blood sample that are protected by the

<sup>28</sup> Notice of Allowance 2, ECF No. 48-5.

 $<sup>^{29}</sup>$  <u>Phillips</u>, 415 F.3d at 1317 (citing <u>Vitronics</u>, 90 F.3d at 1582-83).

patented method. This would be inconsistent with the scope of the patent because the patent applicant clearly overcame the initial indefiniteness determination by articulating these precise characteristics, and the patent examiner deemed these characteristics not measured in the same way by the prior art.

The Court concludes, therefore, that the phrase "the optical density or the absorbance acquired being processed to obtain said speed of sedimentation, viscosity, elasticity and density" is construed as "processing the acquired optical density or absorbance data to obtain the speed of sedimentation, viscosity, elasticity and density."

B. Alifax's Claim Phrase to Construe #2

Claim phrase	Alifax's proposed construction	Defendants' proposed construction	Court's construction
"compare the photometric data with reference parameters contained in the inner memory to determine the speed of sedimentation, viscosity, elasticity and density of the blood sample" ('107 Patent, claim 1; ECF No. 49-36.)	Using the acquired optical density or absorbance data to obtain correlated parameters including the speed of sedimentation, viscosity, elasticity and density, by comparing the data with numerical constants stored in the memory of a processing unit	Plain and ordinary meaning	Processing the acquired optical density or absorbance data to obtain the speed of sedimentation, viscosity, elasticity and density, by comparing the data with numerical constants stored in the memory of a processing unit

Alifax asserts that this claim adds detail that does not exist in the '679 Patent; specifically, that the four parameters are obtained by comparing the data with reference parameters stored in the processing unit. Otherwise, Alifax's arguments regarding the construction of phrase #1 above apply equally to this phrase. Alifax argues that a POSITA would know that "'reference parameters contained in the inner memory' are numerical constants stored in the memory of a processing unit," and are based on syllectogram data, which would not be discerned from the plain language of the claim.

Defendants assert that allowing Alifax's proposed construction would create an additional limitation to the claim because the phrase "numerical constants" does not appear in the '107 Patent. Otherwise, Defendants also advance the same arguments regarding this phrase as they argued above for phrase #1.

articulated The Court's reasoning above for its construction of phrase #1 applies to this phrase to the extent that the phrases contain the same language, especially because the parties' arguments are basically the same. With respect to the part of the claim phrase that refers to comparison ("compare the photometric data with reference parameters contained in the inner memory"), Alifax justifies its proposed construction ("by comparing the data with numerical constants stored in the memory of a processing unit") as necessary detail because a POSITA would understand this to be a part of the inherent detail of the claim. Defendants point out that the term "numerical constants" does not appear in the '107 Patent, but they do not provide any counterargument as to whether a POSITA would understand the claim to mean as Alifax suggests in its proposed construction.

While the specifications in the '107 Patent do not mention "numerical constants" when describing the preferred embodiment for the apparatus, the specification does mention that a comparison is made between the "data acquired" and the

"parameters in the internal memory": "The data acquired are transmitted in real time to the control and processing unit . . . which memorizes them and processes them to obtain the ESR value and the correlated parameters. The data acquired can be compared or integrated with parameters in the internal memory . . . before being processed to determine the ESR value." 30 Based on the arguments and evidence before the Court, there is no reason to believe that a POSITA would not understand the "parameters in the internal memory" to be "numerical constants."

The phrase "compare the photometric data with reference parameters contained in the inner memory to determine the speed of sedimentation, viscosity, elasticity and density of the blood sample" is therefore construed as "processing the acquired optical density or absorbance data to obtain the speed of sedimentation, viscosity, elasticity and density, by comparing the data with numerical constants stored in the memory of a processing unit."

<sup>30 &#</sup>x27;107 Patent col. 6, lines 29-34 (emphasis added).

C. Defendants' Claim Term to Construe #1

Claim term	Alifax's proposed construction	Defendants' proposed construction	Court's construction
"capillary container" ('679 Patent: claims 1, 3, 5-8; '107 Patent: claims 1, 3-6, 9-11.)	Plain and ordinary meaning	a coil-shaped elongated tube	Plain and ordinary meaning

Defendants first argue that the term "capillary container" is indefinite as a matter of law because the patents in suit do not reasonably inform a POSITA how to distinguish between a "capillary," "capillary container," and "container," all of which are mentioned several times in the specifications of both patents. In the alternative, Defendants contend that the term must be construed as "a coil-shaped elongated tube" because this is consistent with both the descriptions in the specification and the illustration of the apparatus in the patents in suit.

Alifax responds that this term does not require any construction, but that if the Court chooses to provide a set definition, then it means nothing more than a "container having a capillary shape" because the term is clearly a compound word with a well-understood meaning. Alifax also argues that, while the Court need not discuss definiteness at this juncture, if it does address Defendants' contention that the term is indefinite, then it should find that it meets the standard for definiteness

because a POSITA would understand the scope of the term with reasonable certainty based on its function in the invention. Alifax asserts that the term is definite and the Court may ascribe the term's plain and ordinary meaning because a POSITA would know that the invention requires a capillary container as the measurement chamber and that the term means a certain kind of container for the blood sample. Alifax also argues "capillary" and "capillary container" are used interchangeably in the specifications and that Defendants' proposed construction of a "coil-shaped elongated tube" is simply not an accurate description.

A review of the two patents reveals that the term "capillary container" appears at least a dozen times in each patent - both in the specification sections and claims. "Capillary" and "container" also appear several times as single words in both patents. When the specification is read as a whole narrative, there is no difficulty in understanding that whether the word "capillary" appears on its own or with "container" next to it, the reference number "12" appears next to the word to indicate that the "capillary" or "capillary container" is part 12 on figure 2 (the illustration of the apparatus provided as part of the patent document). The number refers to the part of the apparatus that the blood passes through, where the light is transmitted through the blood

sample, and where the measurements are actually taken to determine the speed of sedimentation, viscosity, elasticity, and density.

The patents do describe the capillary container in the "preferred embodiment" section as "consist[ing] of a thin conduit, in this case shaped like a coil, defining an inner measuring cell with a thickness of between 0.1 and 3 mm, advantageously 1 mm." Alifax disputes that the capillary container must have a coil shape, and the claim does not limit the term in that way. The Federal Circuit is clear that, while "the specification often describes very specific embodiments of the invention," the claims need not be confined to those embodiments. 32

While the Court could defer Defendants' indefiniteness argument until a later stage in the litigation, the Court finds that the term "capillary container" is clearly not indefinite pursuant to 35 U.S.C. § 112 because it does not fail to inform a POSITA about the scope of the method and apparatus protected by

 $<sup>^{31}</sup>$  `679 Patent col. 5, lines 19-22; `107 Patent col. 5, lines 30-34.

Phillips, 415 F.3d at 1323 ("In particular, we have expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment.").

the patents at issue.<sup>33</sup> In fact, the patent examiner employed the term when she listed her reasons for allowing the '679 Patent claims.<sup>34</sup> If this term was indefinite pursuant to 35 U.S.C. § 112, then the claims would have failed on this point during the patent prosecution phase.

Because the meaning of this term is apparent, the Court need do no more than apply the widely accepted meaning of the words.  $^{35}$ 

<sup>&</sup>lt;sup>33</sup> See Nautilus, 134 S. Ct. at 2124.

 $<sup>^{34}</sup>$  Notice of Allowance 2, ECF No. 48-5 (". . . said method comprising as one component step, instantly interrupting a flow of blood inside a capillary container to substantially simultaneously make detections.").

<sup>&</sup>lt;sup>35</sup> Phillips, 415 F.3d at 1315.

D. Defendants' Claim Phrase to Construe #2

Claim phrase	Alifax's proposed construction	Defendants' proposed construction	Court's construction
"detection being made in correspondence with any point along the length of said capillary container" ('679 Patent: claims 1, 8.)	Plain and ordinary meaning	The detection of optical density can take place at any point along the length of the capillary container through which the blood flows; the detection is not restricted to a fixed point along the length of said capillary	The detection of optical density or absorbance of the blood sample can occur at any location along the length of the capillary container

Defendants argue that their proposed construction for this phrase is in line with the prosecution history for the '679 Patent, in which the applicant had to amend claim 1 to clarify that detection was being made in correspondence with any point (not just a point) along the length of the capillary container. Defendants contend that, without their proposed construction, the phrase would be understood to mean a continuous measurement of "the optical density of the blood sample at a fixed position of the capillary during the flow of blood through the capillary."

Alifax counters that there is nothing unclear or ambiguous in this phrase and that Defendants simply rewrote the phrase. A

POSITA understands the function of a capillary container and so would know that the blood flows through it. Alifax also argues that the plain and ordinary meaning of the phrase indicates that detection could be made at any location along the capillary container. Alifax responds to Defendants' argument regarding the prosecution history by pointing out the detail that the amendment to the claim served to clarify that detection at "any point" referred to the location along the length of the container and not to a time limitation. In addition, Alifax argues that the last part of Defendants' proposed construction is extraneous and unnecessary.

As in Alifax's Claim Phrase to Construe #1, this phrase appears in both claims 1 and 8 of the '679 Patent. The parties are not in disagreement about the meaning of the phrase, but disagree whether the meaning of the claim phrase is plainly understood or whether a rewording of the claim phrase is required to make clear that the optical density detection is not going to occur at the exact same location along the length of the capillary container every time.

To be crystal clear that the claim language regarding

 $<sup>^{36}</sup>$  <u>See</u> Applicant Resp. mailed July 5, 2002, at 4, ECF No. 48-4 (the purpose of replacing "a point" with "any point" was to "more particularly point out and claim that the point is any location along the length of the capillary container").

"detection" that appears in claims 1 and 8 of the '679 Patent refers to location and not time, and that this "detection" can occur at any point along the length of the capillary container, the Court adopts the following construction: The phrase "detection being made in correspondence with any point along the length of said capillary container" is construed as "the detection of optical density or absorbance of the blood sample can occur at any location along the length of the capillary container."

E. Defendants' Claim Term to Construe #3

Claim term	Alifax's proposed construction	Defendants' proposed construction	Court's construction
"pump" ('107	Plain and	a device that	Plain and
Patent: claims	ordinary	raises,	ordinary
1, 2, 9.)	meaning	transfers,	meaning
		delivers, or	
		compresses	
		fluids by	
		suction or	
		pressure or	
		both to act as	
		an instant	
		stoppage pump	

Defendants argue that the word "pump" should be construed by its proposed definition so that the type of pump included in the claims is clear. Defendants contend that if "pump" is given its plain and ordinary meaning, then there is a risk that Alifax will later argue that any kind of pump meets the limitations of the claims. Alifax does not dispute the meaning of the term

"pump" because Defendants largely seek to construe it consistent with a dictionary meaning of the term. Alifax does dispute the part of the construction that limits the meaning "to act as an instant stoppage pump" because Defendants are improperly limiting the claim from the language of the specification.

A "pump" is referred to in three claims of the '107 Patent. In claim 1, the apparatus comprises "a pump in fluid communication with the circuit, the pump configured to circulate the sample of blood inside the circuit and the capillary container; and a stop operatively coupled to the pump, the stop configured to control the operation of the pump to instantly interrupt the circulation of the sample of blood at least inside the capillary container." In claim 2, "[t]he apparatus of claim 1 wherein the stop is electrically coupled to the pump." And, in claim 9, "[t]he apparatus of claim 1 wherein the pump is reversible . . . ."

In the part of the specification that describes the preferred embodiment, the pump is described as that "which can . . . be arranged either upstream or downstream of the capillary, is suitable to activate the sample-withdrawing organ . . . to make the blood sample circulate inside the circuit . . . and the capillary . . .; another function is to interrupt

the flow of the sample instantly."<sup>37</sup> In addition, the pump is reversible "in a preferential embodiment . . . , and allow[s] the blood to circulate inside the circuit in two directions . . . ."<sup>38</sup> This description indicates that the "instant stoppage" proposed by Defendants is only one of the functions of the pump. Defendants simply used a dictionary definition of an ordinary pump and then added the "instant stoppage" limitation. Defendants' proposed construction, therefore, is not supported by the specification because it limits the pump's function in a way that is not limited in the specification. The Court will apply the plain and ordinary meaning to the term "pump."<sup>39</sup>

F. Defendants' Claim Term to Construe #4

Claim term	Alifax's proposed construction	Defendants' proposed construction	Court's construction
"instantly	Plain and	Complete	Plain and
interrupt[]"	ordinary	stoppage of	ordinary
	meaning	flow of blood	meaning
('679 Patent:		in zero elapsed	
claims 1, 5, 7,		time	
8; '107 Patent:			
claim 1.)			

Defendants argue that this term is indefinite because the specification does not inform a POSITA when the flow of blood is instantly interrupted. In the alternative, Defendants argue

<sup>&</sup>lt;sup>37</sup> '107 Patent col. 5, lines 38-42.

<sup>&</sup>lt;sup>38</sup> '107 Patent col. 5, lines 43-45.

<sup>&</sup>lt;sup>39</sup> See Phillips, 415 F.3d at 1315.

that the term should be construed to mean the "complete stoppage of flow of blood in zero elapsed time" because this is consistent with the examiner's statement of reasons for allowing the '679 Patent.

Alifax argues that nothing in the intrinsic record supports Defendants' proposed construction and that the term should be given its plain and ordinary meaning. Alifax contends that "zero elapsed time" is an impossibility and that a POSITA would understand that the meaning of an instant interruption, to the extent it requires further definition, naturally follows from the description of the claimed method and apparatus. In addition, Alifax argues that the term is not indefinite because, based on the intrinsic record, a POSITA would understand how to instantly interrupt the blood flow.

The term appears a few times in the specifications of both patents. For example, when the "pump" is described, an alternative function is "to interrupt the flow of the sample instantly." Also, when the blood sample reaches the capillary, it "is then interrupted by an instant stoppage of the pump . . . . ." In addition, "[a]ccording to a variant" of the method, "at

 $<sup>^{40}</sup>$  '679 Patent col. 5, line 31; '107 Patent col. 5, lines  $42\text{-}43\,.$ 

 $<sup>^{41}</sup>$  '679 Patent col. 6, lines 5-7; '107 Patent col. 6, lines 17-18.

the end of the data-acquisition period, the blood sample is made to circulate in the opposite direction inside . . . the capillary, . . . [t]he flow of blood is then interrupted instantly and a new step is started to acquire the photometric data . . . .  $^{\prime\prime}$  42

As discussed <u>supra</u>, the patent examiner used the term "instantly interrupt" in the statement of reasons for allowing the claims. The patent examiner clearly did not consider this term to be indefinite, or she would not have parroted the language in her statement of reasons for allowing the claims as phrased. In addition, a review of the description of the preferred embodiment in the patents' specifications, including the sections quoted above, reveals the time in the process where the flow of the blood through the capillary container is "instantly interrupted." The patent therefore does "inform, with reasonable certainty, those skilled in the art about the scope of the invention," 43 and is not indefinite.

Turning to Defendants' proposed construction, the Court notes that the specification for the '679 Patent states the following: "The flow of the blood sample is then interrupted by an instant stoppage of the pump . . . commanded by the control

 $<sup>^{42}</sup>$  '679 Patent col. 6, lines 26-31; '107 Patent col. 6, lines 38-43.

<sup>&</sup>lt;sup>43</sup> Nautilus, 134 S. Ct. at 2124.

and processing unit . . .; the considerable deceleration of the flow causes the compaction and subsequent sedimentation of the cells in the blood sample." 44 Defendants' proposed "complete stoppage of flow of blood in zero elapsed time" is not consistent with "deceleration of flow." The Court finds that the apparent meaning of this term may be applied without any additional construction. 45

G. Defendants' Claim Term to Construe #5

Claim term	Alifax's proposed construction	Defendants' proposed construction	Court's construction
"substantially	Plain and	first detection	Plain and
simultaneously"	ordinary	at time of	ordinary
	meaning	complete	meaning
('679 Patent:		stoppage of	
claims 1, 8.)		flow of blood	

Defendants argue that this term is indefinite because it lacks the requisite support in the specification and prosecution history to inform a POSITA about how to "determine whether the detection was made 'substantially simultaneously' with the instant interruption, as opposed to a detection after a time lapse that puts it outside the claims." In the alternative, Defendants argue that the term should be construed to mean "first detection at time of complete stoppage of flow of blood"

<sup>44 &#</sup>x27;679 Patent col. 6, lines 5-9.

 $<sup>^{45}</sup>$  See Phillips, 415 F.3d at 1315.

because the patent's prosecution history reveals that this construction is the only one that makes sense.

Alifax argues that nothing in the intrinsic record suggests that this simple term should be given anything but its plain and ordinary meaning. If the Court chooses to construe it, then Plaintiff requests that the term be given its dictionary meaning (to a large degree happening at the same time). Alifax also argues that a POSITA does not need a special definition to understand what is meant by "substantially simultaneously," and that the term meets the test for definiteness because the specifications provide a clear indication of the scope of the claims in which the terms appear. Alifax contends that a POSITA need only look at the part of the specification that states that the data acquired from the detection "may take a variable period of time to acquire the data, but may reach very limited values with a minimum in the order of 0.1 seconds; normally, it takes between 1 and 30 seconds."46

The term "substantially simultaneously" appears in claims 1 and 8 in the '679 Patent. In both claims, the context is that the detection of the developing optical density of a blood sample over time is made "substantially simultaneously" with the "instant interruption" of the flow of the blood sample inside

<sup>46 &#</sup>x27;679 Patent col. 6, lines 13-16.

the capillary container. The term does not appear in the specification. For the same reasons as those stated <u>supra</u> with respect to Defendants' indefiniteness arguments, the Court finds that "substantially simultaneously" is not indefinite pursuant to 35 U.S.C. § 112, and that Defendants' proposed construction is not consistent with the specifications. Reading the specification and claims together, the Court concludes that the meaning of the term is apparent and needs no more than the application of the widely accepted meaning of these words.<sup>47</sup>

IV. Conclusion

Now that the Court has construed the disputed claim terms and phrases, the parties shall comply with the discovery schedule as modified by the Court on March 20, 2017.

IT IS SO ORDERED.

William E. Smith

Chief Judge

Date: April 27, 2017

<sup>&</sup>lt;sup>47</sup> <u>See</u> <u>Phillips</u>, 415 F.3d at 1315.